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EXAMINER

STUART, COLIN W

ART UNIT

PAPER NUMBER

3771

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/553,643 | <b>Applicant(s)</b><br>CHALVIGNAC, PHILIPPE |  |
|                              | <b>Examiner</b><br>COLIN STUART      | <b>Art Unit</b><br>3771                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/9/09</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This action is in response to the amendment filed 11/6/09. As directed by the amendment claims 1, 4, 6-12, 14-16, and 18-24 have been amended, claims 5 and 17 have been cancelled and no claims have been added. As such, claims 1-4, 6-16, and 18-24 are pending in the instant application.

### *Drawings*

2. The drawings are objected to because of the unlabeled rectangular box(es) shown in Figs. 1-2. The drawings should be provided with suitable descriptive legends. See: 37 CFR 1.84 (n) and (o).

The drawings are objected to because the drawings contain blank boxes and other shapes, which are not widely, recognized engineering symbols. Applicant must supply a suitable legend. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

37 CFR 1.84(n) and (o) permit use of symbols which are not universally recognized, subject to approval by the Office, if they are not likely to be confused with existing conventional symbols, and if they are readily identifiable. In addition, **suitable descriptive legends may be used subject to approval by the Office, or may be required by the examiner where necessary for understanding of the drawing.** (Emphasis added). Thus the examiner may require, on a case-by-case basis, the use of descriptive legends where it is believed that such will facilitate a clear understanding of

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the drawings without undue reliance on the specification for understanding of the subject matter depicted therein. "When possible, a drawing should be so complete that the purpose and operation of the invention may be readily understood by one skilled in the art by means of a mere inspection of said drawing. The necessity of reading the specification in connection with the drawing should be avoided, if possible." See Ex Parte Hartley, 1901 C.D. 247 (Comm'r Pat. 1901).

In the instant case, Figs. 1-2 have boxes and other shapes with lines connecting the shapes together and the use of descriptive legends is necessary because it is believed that such will facilitate a clear understanding of the drawings without undue reliance on the specification for understanding of the subject matter depicted therein. It is clear that Figs. 1-2 are not "so complete that the purpose and operation of the invention may be readily understood by one skilled in the art by means of a mere inspection of said drawing" and that undue reliance on the specification is required for understanding of the subject matter depicted therein.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**4. Claims 1, 3-4, 6-9, 11, 13, 15-16, 18-20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon (5,740,795).**

In regards to claims 1 and 3, Brydon shows a breathing assistance device which includes a turbine 14 to generate a flow of pressurized respiratory gas, a duct ("air delivery tube (not shown)" col. 3 ln. 31) adapted to carry the pressurized gas to a patient, and control means 18 for controlling gas pressure capable of computing a pressure setting for the turbine. Brydon's device also inherently has a speed sensor capable of acquiring a signal corresponding to a rotation speed of a rotating element of the turbine ("motor speed" col. 3 ln. 8). Turbines inherently have a rotating element which is directly related to the speed of the turbine. Brydon's device further includes means of calculation (col. 3 ln. 10-23) connected to the speed sensor to computer the pressure setting of the turbine using the signal from the speed sensor ("speed feedback

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signal 22 is input to the motor controller 18 to provide a signal upon which speed regulation can be based" col. 3 ln. 37-39). Brydon's device includes means of calculation which use speed signals "to detect the points at which the patient starts to inhale or exhale" (col. 3 ln. 15-16) and adapts the level of pressure setting (col. 3 ln. 37-39, but does not teach explicitly teach computing pressure setting based on detecting new inspiratory or expiratory cycles using **only** the speed signal. However, one of ordinary skill in the art at the time the invention was made would have found it obvious to use only the speed signal and would expect the Brydon's device to perform equally as well.

In regards to claim 4, Brydon's device includes calculation means which use the speed signals to compute a pressure setting according to variations in speed ("these measured signals vary" col. 3 ln. 10).

In regards to claims 6, 7, and 11, Brydon's device also includes a "microcomputer where the subsequent signal processing described above is performed" (col. 4 ln. 38). This microcomputer employs signal processing programs to detect "the start of inhalation and exhalation" (col. 3 ln. 67 - col. 4 ln. 1). The programs use "previously determined pressure/flow/speed characteristics of the turbine system" (col. 3 ln. 12-14), which are stored in a memory of the device's control means 18, along with the actual instantaneous speed signal 22 and "threshold value for detecting inhalation and exhalation" (col. 4 ln. 25-26). Brydon's reference discloses an "instantaneous power signal" (col. 3 ln. 60) which is employed in the signal processing and is directly related to the instantaneous speed of the turbine. The speed signal is the speed

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bearing as in claim 7 because direction of the flow can be ascertained in that a positive value would indicate flow going into the patient.

In regards to claim 8, Brydon's reference has everything as claimed including speed sensor and a computer (calculation means) which uses previously determined values which are stored in a memory of the device's control means 18. Brydon lacks a detailed description of using a program to detect an inspiratory cycle using a comparison between a memorized speed value representative of a speed at the end of an expiratory cycle and an actually measured instantaneous speed. However, the feature of comparing the predetermined speed to the real time speed is well known in the art for obtaining desired speed. In addition, using a program to calculate or determine the desired speed is common practice and is necessary for carrying out the calculations. Furthermore, Brydon's reference is capable of obtaining a speed at the end of expiratory cycles. Thus, the feature of having a program to compare the memorized speed value at the end of the expiratory cycle and the actual measured speed fails to patentably define over the prior art.

In regards to claims 9 and 21, the Brydon's reference employs a microcomputer to perform signal processing and comparison as discussed above but is silent as to using several programs for comparison. However, one of ordinary skill in the art at the time of the invention would have found it obvious to use various programs simultaneously for comparison to increase the accuracy of the inhalation/exhalation detecting process.

In regards to claim 13, Brydon's device uses a microcomputer, which is a microprocessor, to perform signal processing and comparison of the speed signals to detect inhalation/exhalation cycles.

In regards to claims 15-16, 18-20, and 23-24, Brydon lacks a detailed description of the claimed method steps. However, Brydon's system has the same structure as claimed. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made upon seeing Brydon's system, that the system would be able to perform the claimed method steps.

**5. Claims 10, 12, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon (5,740,795) as applied to claim 6, 11, or 18 above, and further in view of Rapoport et al. (5,803,066).**

In regards to claim 10 and 22, the Brydon's reference teaches all the limitations as discussed above, but, as best understood, is silent as to providing that the device is configured to be disabled to compensate for the momentary pause between inspiratory and expiratory cycles. However, Rapoport teaches a breathing assistance device and control method which includes a pause state which allows the "machine is in transition from INSP to EXP, or from EXP to INSP" (Rapoport col. 7 ln. 56-57) for a determined duration following the start of the cycle. Therefore, one of ordinary skill in the art at the time the invention was made would have found it obvious to modify the Brydon's device and method to include a disabling means, or pause state, as taught by Rapoport in order to provide a more accurate control method for the breathing assistance device.



In regards to claim 12, the Brydon's reference teaches all the limitations as discussed above including previously determined and stored in memory speed values, but is silent as to the memorized turbine speed values being maximum values for an inspiratory cycle. However, Rapoport teaches a breathing assistance device and control method in which the "system determines the maximum inspiratory flow value" (Rapoport col. 8 ln. 39-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brydon's device and method to also use memorized maximum turbine speed values for an inspiratory, as taught by Rapoport, in its comparison method in order to provide a more accurate control method as the modified method would be taking measurements from points through out the respiration cycles as opposed to focusing on the transitions from inspiratory to expiratory cycles.

**6. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon (5,740,795) as applied to claim 1 or 18 above, and further in view of Farrugia et al. (6,332,463).**

In regards to claim 2, the Brydon's reference teaches all the limitations as discussed above, but is silent as to the speed sensor being a Hall effect sensor. However one of ordinary skill in the art at the time of the invention would have found this to be a matter of obvious design choice as a Hall effect sensor is well-known in the art and further taught by Farrugia's breathing assistance control method (Abstract line 3).

In regards to claim 14, Brydon's reference teaches all the limitations as discussed above including a circuit which connects the speed sensor, calculation

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means, and turbine for computing the speed setting input for the turbine (Brydon col. 4 ln. 36-48, but is silent as to the pressure-regulating "feedback loop" (Brydon col. 2 ln. 58) further including a pressure sensor on the duct. However, Farrugia teaches a breathing assistance device and control method which includes a pressure sensor (42 Farrugia) which is connected to breathing tube, or duct, (40 Farrugia). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Brydon's reference to include a pressure sensor as taught by Farrugia in order to provide a more direct, and accurate, measurement of the pressure of the breathing gas delivered to a patient.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1 and 17 have been considered but are moot in view of the new ground(s) of rejection.

The arguments with respect to the Brydon reference not teaching the claimed invention and its limitations, especially due to the filtering aspects, is not well-taken as there is no claim language regarding the presence, or lack thereof, of filtering elements/methods.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art:

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Jafari et al. (6,626,175), Champain et al. (5,443,061), and Servidio et al. (5,927,274) are all related to ventilation regulation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771